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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,343	11/01/2005	Akira Kato	1089.0590000/MAC	4524
26111 7590 03/29/2010 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
EXAMINER				
RICCI, CRAIG D				
ART UNIT		PAPER NUMBER		
1628				
MAIL DATE		DELIVERY MODE		
03/29/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/555,343

Applicant(s)

KATO ET AL.

Examiner

CRAIG RICCI

Art Unit

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18, 21-23 and 28-43 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 11/20/2009

DETAILED ACTION

Status of the Claims

1. The amendments filed 12/18/2009 were entered.

Response to Arguments

2. Applicants' arguments, filed 12/18/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Arguments directed to withdrawn rejections are hereby rendered moot. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Instant claims 28-43 are rejected rejected under 35 U.S.C. 103(a) as being unpatentable over *Miyake et al* (JP 63-313736) – certified translation provided – in view of *Driskell* (Sports Nutrition, Page 75, 2000).**

6. Instant claim 28 is drawn to a freeze-dried preparation comprising methylcobalamin or a pharmacologically and an excipient, wherein said excipient comprises at least one sugar (selected from glucose, fructose, maltose, lactose, sucrose and trehalose) in an amorphous state. More specifically, the amorphous sugar is present in an amount of at least 20% by weight, based on the total weight of the excipient, as recited by instant claim 29. Additionally, as recited by instant claim 30, the freeze-dried preparation further comprises a pH adjuster and, as recited by instant claim 31, further comprises an anti-oxidant. Moreover, as recited by instant claim 33, the methylcobalamin is also in an amorphous state. As thus summarized, the invention reads on claims 28-36.

7. *Mayake et al* disclose a preparation comprising vitamin B₁₂ (10 µg), lactose (50 µg), an antioxidant (Vitamin E (10 mg)), and a pH adjuster (NaOH) which is then freeze-dried (Pages 8-9, Practical Example 1). Although *Mayake et al* refer to Vitamin B₁₂ as “cyanocobalamine” (Page 6, Table 1), it is understood that vitamin B₁₂ would necessarily comprise methylcobalamin also (i.e., the active form of vitamin B₁₂ as evidenced by *Driskell* (Page 75)). However, even *assuming arguendo* that the vitamin B₁₂ disclosed by *Mayake et al* does not comprise methylcobalamin, the ordinarily skilled artisan would have found it *prima facie* obvious to replace cyanocobalamin in the formulation taught by *Mayake et al* with methylcobalamin in view of *Diskell*. The skilled artisan would have been motivated to formulate the vitamin preparation comprising vitamin B₁₂ taught by *Mayake et al* using methylcobalamin in view of

Diskell, who teaches that methylcobalamin (not cyanocobalamin) is the active form of vitamin B₁₂.

8. As such, *Mayake et al* in view of *Driskell* disclose a freeze-dried preparation comprising methylcobalamin and an excipient (i.e., lactose). Although *Mayake et al* do not specifically disclose that the lactose in the freeze-dried preparation is amorphous or that the methylcobalamin in the freeze-dried preparation is amorphous, it is asserted – absent evidence to the contrary – that the lactose and methylcobalamin would necessarily be in an amorphous state in the freeze-dried preparation taught by *Mayake et al* in view of *Driskell*. As stated in *In re Best, Bolton, and Shaw*, “Where... the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product” 195 USPQ 430, 433, 562 F2d 1252 (CCPA 1977). In the instant case, the claimed and prior art products are substantially identical. Accordingly, it is asserted that the prior art freeze-dried product would necessarily comprising amorphous lactose and amorphous methylcobalamin, absent evidence to the contrary. See also *In re Fitzgerald* 205 USPQ 594, 597, 619 F2d 67 (CCPA 1980): the burden is shifted to the applicants to “prove that subject matter shown to be in the prior art does not possess characteristic relied on.

9. As such, instant claims 28-36 are rejected as *prima facie* obvious.

10. Instant claims 37-43 are all drawn to a freeze dried preparation comprising methylcobalamin and an excipient wherein the freeze dried preparation is obtained by a specific

**PRODUCT-BY-PROCESS CLAIMS ARE NOT
LIMITED TO THE MANIPULATIONS OF THE
RECITED STEPS, ONLY THE STRUCTURE
IMPLIED BY THE STEPS**

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

process. As stated by MPEP 2113: . In the instant case, the instantly claimed product in the product-by-process claim is obvious from a product of the prior art as previously discussed in view of *Mayake et al* in view of *Driskell*. Accordingly, the obvious product as obtained by the process recited by claims 37-41 is rejected as *prima facie* obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan "Paddy" Sreenivasan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1628

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642